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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,991	05/08/2007	**Andrew Jonathan Humberstone**	025217-0147	1892

22428 7590 08/02/2010

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EXAMINER	
BOSWORTH, KAMI A	
ART UNIT	**PAPER NUMBER**
3767	
MAIL DATE	**DELIVERY MODE**
08/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,991	HUMBERSTONE ET AL.	
	Examiner	Art Unit	
	KAMI A. BOSWORTH	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-5, 7-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoendorfer (US Pat 5,944,662) in view of Dobin-Assouly et al. (PG PUB 2005/0244438).

3. Re claim 1, Schoendorfer discloses a method for inhibiting the percutaneous absorption of a drug (Table 1) that has been administered to a transdermal administration site (sweat gland) of a subject (Col 9, Line 33 - Col 10, Line 15), the method comprising: applying to skin 12 (Fig 2a) of the subject at the transdermal administration site, a device 11 (Fig 2) comprising a membrane 20 (Fig 2a) for contacting the skin of the subject (as seen in Fig 2a) and coated on the skin contacting side with a layer of an adhesive (Col 9, Line 2) that is permeable to the drug, such that the layer of adhesive contacts the transdermal administration site, such that drug is extracted from the skin through the layer of adhesive (Col 9, Lines 2-7 and Col 11, Lines 38-44), whereby the amount of drug transferred to the blood stream of the subject is reduced (inherent since an amount of the drug is being removed from the body; less drug in the body inherently means that less drug can be transferred to the blood

stream). Schoendorfer does not explicitly disclose that drug was topically administered or that the subject (a) has been administered an overdose of the drug or (b) has experienced one or more adverse side effects from the drug. Doblin-Assouly et al., however, teaches the topical removal of a topically-administered drug in response to an overdose of the drug (Para 6,10) for the purpose of treating the subject (Para 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schoendorfer to include administering treatment in response to an overdose of a drug, as taught by Dobin-Assouly et al., for the purpose of treating the subject (Para 6).

4. Re claim 3, Schoendorfer discloses that the membrane is applied to the whole of the transdermal administration site (sweat gland; Col 9, Lines 49-51).

5. Re claim 4, Schoendorfer discloses that the drug has been administered so as to form a reservoir (sweat gland) of the drug in the skin of the subject, and the application of said device results in the drug being extracted from the skin to reduce the total dose of drug which would otherwise be administered transdermally (Col 9, Lines 49-55).

6. Re claim 8, Schoendorfer does not explicitly disclose that the adhesive layer comprises a material selected from the group consisting of acrylics, polyethylenes, polysiloxanes, polyisobutylenes, polyacrylates, polyurethanes, plasticized ethylene vinyl acetate copolymers and tacky rubbers. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schoendorfer to include such a material since it has been held to be within the general

skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

7. Re claim 10, Schoendorfer discloses that the device is applied to the site of transdermal administration within 24 hours of transdermal administration of the drug (Col 33, Lines 46-51).

8. Re claim 11, Schoendorfer does not explicitly disclose that drug has been topically administered to the transdermal administration site prior to the device being applied thereto. Doblin Assouly et al., however, teaches the topical administration of an overdose drug (Para 10) administered to a transdermal administration site prior to removing the drug (Para 6,10) for the purpose of treating the subject (Para 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schoendorfer to include topically administering the drug prior to the device being applied thereto, as taught by Dobin-Assouly et al., for the purpose of treating the subject (Para 6).

9. Re claim 12, Schoendorfer discloses that the device further comprises at least one layer 22 (Fig 2a) on the side of said membrane remote from the side applied to the skin (as seen in Fig 2a) and wherein a reservoir of solvent 31 (Fig 2a) is provided between said at least one layer and said membrane (as seen in Fig 2a) wherein said drug is at least partially soluble in the solvent (Col 9, Lines 45-55).

10. Re claim 13, Schoendorfer discloses that the solvent is selected from a group consisting of alcohols, alkanes, ethers, ketones, chlorinated hydrocarbons and nitriles (Col 3, Lines 37-43).

11. Re claim 14, Schoendorfer does not explicitly disclose the solvent is selected from a group consisting of ethanol and its derivatives, methanol, chloroform, isopropyl alcohol and mixture of two or more thereof. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schoendorfer to include such a material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416.*

12. Re claim 15, Schoendorfer discloses that the membrane remains adhered to the skin at the site of transdermal administration for a period of at least 12 hours (Col 33, Lines 50-51).

13. Re claim 17, Schoendorfer discloses that the drug comprises at least one selected from the group consisting of anti-diarrhoeals, anti-hypertensives, calcium channel blockers, anti-arrhythmics, anti-angina agents, beta-adrenergic blocking agents, cardiotonic glycosides, adrenergic stimulants, vasodilators, anti-migraine preparations, anticoagulants, thrombolytic agents, analgesics, hypnotics, anti-anxiety agents, neuroliptic agents anti-psychoticagents, antidepressants, CNS stimulates, anti-Alzheimer agents, anti-Parkinson agents, anticonvulsants, anti-emetics, non-steroidal anti-inflammatory agents, anti-rheumatoid agents, muscle relaxant agents for treatment of gout, agents for treatment of hyperuricaemia, oestrogens, progesterone, anti-androgens, anti-oestrogens, androgens, anti- alopecia agents, 5-alpha reductase inhibitors, carbosteroids, pituitary hormones, hypoglycaemic agents, thyroid hormones, pituitary inhibitors, ovulation inducers, anti-muscarinic agents, diuretics, antidiuretics,

obstetric drugs, prostaglandins, antimicrobials, anti-tuberculosis drugs, anti-malarials, antivirals, anthelmintics, cytotoxic agents, anorectic agents, agents used in hypocalcaemia, antitussives, expectorants, decongestants, bronchospasm relaxants, antihistamines, local anaesthetics, neuromuscular blockers, smoking cessation agents, insecticides, dermatological agents, nutritional agents, keratolytics, psychic-energisers, anti-acne agents, anti-itch agents and anti-cholinergic agents (Table 1).

14. Re claim 1, Schoendorfer discloses a method for inhibiting the percutaneous absorption of a drug (Table 1) that has been administered to a transdermal administration site (sweat gland) of a subject (Col 10, Line 17—Col 11, Line 30), the method comprising: applying to skin 12 (Fig 2a) of the subject at the transdermal administration site, a device (Fig 3) comprising a membrane 32 (Fig 3a) for contacting the skin of the subject (as seen in Fig 3a) and coated on the skin contacting side with a layer of an adhesive (Col 9, Line 2) that is permeable to the drug, such that the layer of adhesive contacts the transdermal administration site, such that drug is extracted from the skin through the layer of adhesive (Col 9, Lines 2-7 and Col 11, Lines 38-44), whereby the amount of drug transferred to the blood stream of the subject is reduced (inherent since an amount of the drug is being removed from the body; less drug in the body inherently means that less drug can be transferred to the blood stream). Schoendorfer does not explicitly disclose that the drug is topically administered or that the subject (a) has been administered an overdose of the drug or (b) has experienced one or more adverse side effects from the drug. Doblin Assouly et al., however, teaches the topical removal of a topically-administered drug in response to an overdose

of the drug (Para 6,10) for the purpose of treating the subject (Para 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schoendorfer to include administering treatment in response to an overdose of a drug, as taught by Dobin-Assouly et al., for the purpose of treating the subject (Para 6).

15. Re claim 7, Schoendorfer discloses that the device comprises a semi-permeable layer 20 (Fig 3a) comprising cellulosic membrane (Col 7, Lines 27-33).

16. Re claim 9, Schoendorfer discloses that the membrane is less than 2 mm thick (Col 11, Lines 3-4).

17. Re claim 5, Schoendorfer discloses a method for removal of a drug (Table 1) from a reservoir (sweat gland) thereof within the skin of a subject following administration of the drug to a site on the skin 12 (Fig 2a) of the subject (Col 9, Line 33 - Col 10, Line 15), the method comprising: applying a device 11 (Fig 2) comprising a membrane 20 (Fig 2a) to the site of transdermal administration of the drug, wherein the device comprises a layer of adhesive (Col 9, Line 2) that is permeable to the drug, such that the layer of adhesive contacts the site of transdermal administration of the drug, such that drug is extracted from the skin through the layer of adhesive (Col 9, Lines 2-7 and Col 11, Lines 38-44). Schoendorfer does not explicitly disclose that drug is transdermally applied. Doblin Assouly et al., however, teaches the topical removal of a transdermally-applied drug in (Para 10) for the purpose of treating the subject (Para 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schoendorfer to include removing a transdermally

applied the drug, as taught by Dobin-Assouly et al., for the purpose of treating the subject (Para 6).

18. Re claim 16, Schoendorfer discloses a method of reducing the effect of administration of a drug (Table 1) to a site of skin 12 (Fig 2a) of a subject to form a reservoir (sweat gland) of drug in the skin (Col 9, Line 33—Col 10, Line 15), the method comprising: providing a membrane assembly 11 (Fig 2) for contacting the site of skin: the membrane assembly comprising (a) a selectively permeable membrane 20 (Fig 2a) for making contact with the skin to allow ingress of the drug and provided with an adhesive layer (Col 9, Lines 2-7) on the skin contacting side thereof, (b) a backing layer 22 (Fig 2a) and (c) a reservoir of solvent 31 (Fig 2a) between the backing layer and membrane, wherein the drug is at least partly soluble in the solvent (Col 9, Lines 45-55); and applying the adhesive layer of the membrane assembly to the site of skin of transdermal administration (Col 9, Lines 37-39), whereby the drug is extracted from the skin through the adhesive layer into the membrane assembly (Col 11, Lines 38-44). Schoendorfer does not explicitly disclose that drug was transdermally administered or that the subject has been administered an overdose of the drug. Doblin Assouly et al., however, teaches the topical removal of a transdermally-administered drug in response to an overdose of the drug (Para 6,10) for the purpose of treating the subject (Para 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schoendorfer to include administering treatment in response to an overdose of a drug, as taught by Dobin-Assouly et al., for the purpose of treating the subject (Para 6).

19. Re claim 20, Schoendorfer discloses that the membrane assembly further comprises a solvent impermeable layer 28 (Fig 2a; Col 9, Lines 45-58) adjacent the side of said membrane remote from the adhesive (as seen in Fig 2a).

Response to Arguments

20. Applicant's arguments with respect to claims 1, 3-5, 7-17 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767